

Dockets Management Branch (HFA-305)

Docket No. 98N-1265

Food and Drug Administration

5600 Fishers Lane

Rockville, MD 20857

4424 '99 MAY 19 P4:34

May 17, 1999

To whom it may concern at the FDA,

I have been informed by my specialized pharmacist (Madson Pharmacy in Wisconsin) which makes my compound Progesterone, that I may not be able to get this critical medication needed for a normal functioning life, on a monthly basis.

I am a Michigan resident and I am a PMS sufferer. My symptoms include depression, mood swings, emotional lability, and anxiety, all of which compound Progesterone alleviates. When I take this medication (100MG 3x daily from day 14-end of menses), my mood evens out, and I am able to cope better with life's stresses ^{because} I do not overreact. Before taking compound Progesterone, I had great difficulty dealing with work and family situations. If this compound form of Progesterone is no longer

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available to me, my life would be in chaos.
I have already tried 3 or 4 different antidepressants
none of which have worked. So you see - I am
out of options. You will be taking away some-
thing that works for me.

My physician originally gave me a prescription for the compound Progesterone. One year later, when it was time for my refill, he wanted me to try the commercial form of Progesterone. At the same time he gave me a prescription for the compound form (stating that if I did not like the commercial form, I could continue taking the compound Progesterone. After trying the commercial Progesterone for 1 month, I felt that my symptoms were not
relieved, and quickly I faithfully returned to
the compound Progesterone - because it worked.

I feel that the definition of "inordinate amount" contained in the MOU draft is outrageous and ridiculous, because as a consumer, I have found something that works for me. Just because the medication is shipped across state lines, the FDA will only allow relief of PMS symptoms to a select number of people. This frightens and angers me,

because this would be taking away any possibility to live an emotionally stable life each month.

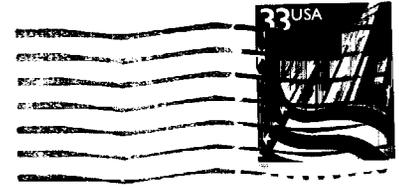
This draft would greatly compromise my quality of life because I would not be able to obtain the compound Progesterone my doctor has prescribed for me.

In closing, if this draft is enacted, you would be taking away my ^{quality of} life.

Susan Stollstemer

Very Concerned / Outraged PMS Sufferer

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